Dr. J. Doe – NIH R01 Submission

Multidisciplinary Studies (R01 Clinical Trial Optional)

General Formatting Information

- Font Type: Arial, Helvetica, Palatino Linotype, or Georgia typeface in black font color
- Font Size and Spacing: 11-point or larger.
- A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes may smaller font in black font color.
- Margins: At least one-half (1/2) inch at the top, bottom, left and right for all pages.
- Header and Footer: Do not include any information in the header or footer of the attachments. The header and footer will be system-generated.
- Application must be submitted by the OSP Officer via ASSIST by 5:00 pm central time on the due date.
- ASSIST ID: 0000000 https://public.era.nih.gov/assist

Application Components *(Refer to the FOA for specific instructions)*

Section of Application	Page Limits (If different from FOA, FOA supersedes)	Action
SF-424 Application/R&R Cover		GDRM
a. Project Title	Limited to 200 characters (including spaces and punctuation) Examining the effect of High-intensity Exercise to Attenuate Cognitive function Limitations and Train exercise Habits in older people living with HIV (HEALTH-Cog)	PI
Other Project Information		
a. Project Summary/Abstract	30 lines including title	PI
b. Project Narrative	3 sentences; relevance to public health	PI
c. Bibliography & References Cited (in Research Plan and Human Subjects/Clinical Trials Information)	No page limit, concise	PI
d. Facilities & Other Resources	No page limit, concise (GDRM to provide template)	PI/GDRM
e. Equipment (if applicable)	No page limit, concise	PI
Sr./Key Person Profile		
a. Biographical Sketches	5 pages per biosketch	PI
b. Other Support (K awards)	3 pages per Other Support	
R&R Budget / Budget Justification		
a. Budget / Budget Justification	No page limit, concise	PI/GDRM
Research Plan		
a. Specific Aims	1 page limit	PI
b. Research Strategy	12 page limit	PI
c. Consortium/Contractual Arrangements (if applicable)	No page limit, concise	PI
d. Letters of Support (if applicable)	No page limit, concise	PI
e. Resource Sharing Plan(s)	No page limit, concise	PI
f. Other Plans	No page limit, concise	
g. Appendix (if applicable)	Maximum of 10 pdfs allowed	PI
Human Subjects and Clinical Trials (see handout provided)	Forms H	

a. Use of Human Specimens and/or Data	Does any of the proposed research in the application involve human specimens and/or data? (Yes or No) *Add an attachment that provides an explanation for any use of human specimen and/or data NOT considered to be human subjects research.*	PI

b. Are Human Subjects involved? **c. If Yes, Is the project exempt from federal regulations?** **d. Exemption Number:**	Yes or No Yes or No Select an Exemption Number: 1-8	PI
e. If No to Human Subjects:	**SKIP THE REST OF THE PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM**	PI
f. Study Record(s)	Attach human subject study records using unique filenames.	PI
1.1. Study Title	Each study title must be unique	PI
1.2. Is the Study Exempt from Federal Regulations	Yes or No	PI
1.3. Exemption Number	Select an Exemption Number: 1-8	PI
1.4. Clinical Trial Questionnaire	Does this study meet the definition of a Clinical Trial? (Answer 4 questions)	PI
1.5. Provide Clinical Trials.gov Identifier for this trial, if applicable	If Applicable	PI
2.1. Conditions or Focus of Study	Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study	PI
2.2. Eligibility Criteria	Up to 15,000 characters	PI
2.3. Age Limits	Enter the minimum and maximum ages (or No Age Limit)	PI
2.3.a. Inclusion of Individuals Across the Lifespan	Add attachment along with an Inclusion Enrollment Report (IER) No page limit, concise	PI
2.4. Inclusion of Women and Minorities	Add attachment along with an Inclusion Enrollment Report (IER) No page limit, concise	PI
2.5. Recruitment and Retention Plan	No page limit, concise	PI
2.6. Recruitment Status: Choose from (not yet recruiting, recruiting, enrolling by invitation, active-not recruiting, completed, suspended, terminated, withdrawn)	Select from dropdown menu	PI
2.7. Study Timeline or Description	No page limit, concise	PI
2.8. Enrollment of First Participant	Enter date and indicate Anticipated or Actual	PI
2.9. Inclusion Enrollment Report(s)	Required for EACH STUDY – Add New Inclusion Enrollment Report - maximum of 20 reports	PI
3.1. Protection of Human Subjects	No page limit, concise	PI
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	Yes, No, or N/A If yes, describe the single IRB plan	PI
3.3. Data and Safety Monitoring Plan	No page limit, concise	PI
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	Yes or No	PI
3.5. Overall Structure of the Study Team	No page limit, concise	PI

4.1. Study Design		
4.1.a. Detailed Description	Up to 32,000 characters	PI
4.1.b. Primary Purpose	Select from dropdown menu	PI
4.1.c. Interventions	Add new intervention	PI
4.1.d. Study Phase	Select from dropdown menu	PI
Is this an NIH-defined Phase III Clinical Trial?	Yes or No	PI
4.1.e. Intervention Model	Select from dropdown menu	PI
4.1.f. Masking	Yes or No Choose One: Participant, Care Provider, Investigator, Outcomes Assessor	PI

4.1.g. Allocation	Select from dropdown menu	PI
4.2. Outcome Measures	Add New Outcome	PI
4.3. Statistical Design and Power	Add attachment	PI
4.4. Study Participation Duration	Fill in blank	PI
4.5. Will the study use an FDA-regulated intervention?	Yes or No	PI
4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status	Add attachment	PI
4.6 Is this an applicable clinical trial under FDAAA	Yes or No	PI
4.7 Dissemination Plan	Add attachment	PI
Project/Performance Site Location(s)		GDRM
PHS Assignment Request Form	Optional	PI

Send final items to Dan Roberts (drberts@uab.edu) or Megan Cardenas (mccarden@uab.edu) immediately upon completion.

Grant Specific Information *(Refer to FOA for Specific Details)*

- Application Due: September 7, 2022
- Scientific Merit Review: October/November 2022
- Advisory Council Round: January 2023
- Earliest Project Start Date: April 1, 2023

Project Period: The maximum project period is 5 years.

Budget:

- Requests of $500,000 or more in direct costs must contact a Scientific/Research Contact at least 6 weeks before submitting application
- Indirect Cost applied at a rate of 48.5% MTDC for On-Campus Research
- Cost Share: Not Required

Grant Development, Review, and Management (GDRM) Information

Submitting Items to GDRM

1. Only submit final versions of the required items rather than submitting draft versions.
2. Please submit the required items upon completion rather than waiting to submit at the end of the process
3. Additional items may be requested throughout the application process.
4. Submission of GDRM required items early in the proposal process will allow the investigator to focus on the technical aspects of the proposal later in the process.

Post Submission

After submission, you will receive a series of emails from the OSP Officer. Feel free to check the assembled

application in eRA Commons.

When you receive your Summary Statement from the sponsor, please forward to Cathy Tarver cotarver@uab.edu